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(71) Applicant (*for all designated States except US*):
RESMED LTD [AU/AU]; 1 Elizabeth Macarthur Drive,
Bella Vista, New South Wales 2153 (AU).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **VELISS, Lee, James** [AU/AU]; ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **DOHERTY, Renee, Frances** [AU/AU]; ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **HOWARD, Scott, Alexander** [AU/AU]; ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **WELLS, Alicia, Kristianne** [AU/AU]; ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **CARROLL, Fiona, Catherine** [IE/AU]; ResMed Ltd, 1 Elizabeth Macarthur Drive, Bella Vista, New South Wales 2153 (AU). **GILLIVER, David, Mark** [NZ/AU]; 11 Arkaringa Crescent, Black Rock, Victoria 3193 (AU).

LINDSAY, Brett, Thomas [NZ/AU]; 6 Yanina Court,
Glen Waverley, Victoria 3150 (AU).

(74) Agents: **DAVIDSON, Geoffrey, Robert** et al.; Halford &
Co, 1 Market Street, Sydney, New South Wales 2000
(AU).

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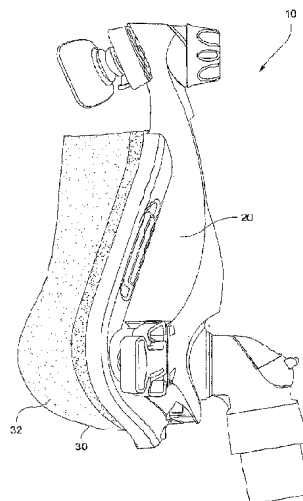
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(54) Title: AN INTERFACE INCLUDING A FOAM CUSHIONING ELEMENT

Fig. 1



(57) Abstract: A respiratory mask assembly includes a frame (20) having a channel and a cushioning element (30) including a clip portion adapted for interference seal and retention in the channel. The cushioning element includes an interfacing portion constructed from foam and having a wider width than the clip portion.

AN INTERFACE INCLUDING A FOAM CUSHIONING ELEMENT

CROSS-REFERENCE TO APPLICATION

[0001] This application claims the benefit of Australian Provisional Patent Application No. AU 2008901056, filed March 4, 2008, which is incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The present invention relates to an interface between a human and a piece of equipment, for example a mask, that includes a foam-based cushioning element.

BACKGROUND OF THE INVENTION

[0003] In a number of fields, such as respiratory therapy, apparatus for delivery of therapy includes a more rigid component defining a structure and a soft, cushioning component positioned between the patient and the rigid component.

[0004] In the case of a respiratory device, the more rigid component may be a mask frame defining a nose-receiving chamber. The mask frame may include a flange around its periphery. The cushioning component may be glued to the flange. See U.S. Patent Application Publication US 2003/0168063.

[0005] The cushioning component may form an air tight seal with the skin of the patient in some forms of respiratory therapy. In other devices, for example headphones, it may not be necessary for an air tight seal to be formed.

[0006] Other known masks that include foam cushioning elements include the following Fisher and Paykel masks: ACLAIM mask, FLEX-FIT 405, FLEX-FIT 407, and FLEX-FIT 431.

SUMMARY OF THE INVENTION

[0007] A first aspect of the invention is to provide a patient interface with a foam cushioning element.

[0008] Another aspect of the invention is to provide a patient interface with a removable foam cushioning element.

[0009] Another aspect of the invention is to provide a patient interface system with at least two different types of removably replaceable cushioning elements.

[0010] Another aspect of the invention is to include a cushioning element having portion adapted for engagement with a more rigid component.

[0011] Another aspect of the invention is to provide a respiratory mask assembly including a frame and a cushioning element wherein the cushioning element includes a foam-based interfacing portion and a clip portion adapted for removable engagement with the frame portion.

[0012] Another aspect of the invention is to provide a support structure for a cushioning element that supports the cushioning element on one side and allows movement on another side.

[0013] Another aspect of the invention relates to a cushion for a respiratory mask including a clip portion and an interfacing portion wherein the interfacing portion is constructed from a foam material and the clip portion is narrower than the interfacing portion.

[0014] Another aspect of the invention relates to a respiratory mask assembly including a frame having a channel and a cushioning element including a clip portion adapted for interference seal and retention in the channel. The cushioning element includes an interfacing portion constructed from foam and having a wider width than the clip portion.

[0015] Another aspect of the invention relates to a respiratory mask assembly including a frame having a channel and a removably replaceable interfacing structure including a clip portion adapted for interference seal and retention in the channel. The interfacing structure includes a cushion component constructed from foam.

[0016] Another aspect of the invention relates to a mask system including a common frame and at least a first cushion constructed from foam and a second cushion constructed from silicone. The first and second cushions are each structured to removably attach to the frame.

[0017] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying

drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0019] Fig. 1 shows a side view of a mask assembly including a foam cushioning element according to an embodiment of the invention;

[0020] Fig. 2 shows a schematic diagram of a channel of a portion of a mask frame and a clip portion of a cushioning element retained by an interference fit according to an embodiment of the invention;

[0021] Figs. 3a, 3b, and 3c show a range of rib engagement fitting arrangements between a mask frame and a clip portion of a cushioning element according to embodiments of the invention;

[0022] Fig. 4a shows a patient contacting side of a cushioning element according to an embodiment of the invention;

[0023] Fig. 4b shows a bottom view of the cushioning element of Fig. 4a;

[0024] Fig. 4c shows a top view of the cushioning element of Fig. 4a;

[0025] Fig. 4d shows a side view of the cushioning element of Fig. 4a;

[0026] Fig. 4e shows a frame contacting side of the cushioning element of Fig. 4a;

[0027] Fig. 4f shows a patient contacting side isometric view of the cushioning element of Fig. 4a;

[0028] Fig. 4g shows a frame contacting side isometric view of the cushioning element of Fig. 4a;

[0029]

[0030] Fig. 5a is a plan view showing a die cut cushioning element wherein the clip portion includes a slot for engagement with the frame according to an embodiment of the invention;

[0031] Fig. 5b is an isometric view of the cushioning element shown in Fig. 5a;

[0032] Fig. 5c is an assembly view of the cushioning element shown in Fig. 5a with a mask frame;

- [0033] Fig. 6a shows a cross-section from a prior art nasal mask with foam cushion;
[0034] Fig. 6b shows a detail in the nasal bridge region of the mask of Fig. 6a;
[0035] Fig. 7a shows an elevation view detail from the frame side of the cushioning element shown in Fig. 4e;
[0036] Fig. 7b is a cross-section along line 7b-7b of Fig. 7a;
[0037] Fig. 7c is a cross-sectional view showing the cushioning element of Figs. 7a and 7b in use; and
[0038] Fig. 8 is a cross-sectional view showing the assembly of the cushioning element of Figs. 7a and 7b and a frame according to an embodiment of the invention.

DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0039] The following description is provided in relation to several embodiments which may share common characteristics and features. It is to be understood that one or more features of any one embodiment may be combinable with one or more features of the other embodiments. In addition, any single feature or combination of features in any of the embodiments may constitute additional embodiments.

[0040] In this specification, the word “comprising” is to be understood in its “open” sense, that is, in the sense of “including”, and thus not limited to its “closed” sense, that is the sense of “consisting only of”. A corresponding meaning is to be attributed to the corresponding words “comprise”, “comprised” and “comprises” where they appear.

[0041] The term “air” will be taken to include breathable gases, for example air with supplemental oxygen.

Interconnection of Cushioning Element and Apparatus

[0042] In accordance with an embodiment of the present invention, a removable interconnectable cushioning element (also referred to as a cushion element or cushion) is provided. The cushioning element preferably includes a soft resilient foam interfacing portion for contacting a human. The cushioning element is constructed and arranged for removable interconnection with the rest of the apparatus, for example a respiratory mask.

[0043] The ability to removably connect the cushioning element enables one to replace the cushioning element should it become soiled and/or uncomfortable. It also

facilitates trial of different forms of cushioning element. One form of cushioning element, for example a foam-based cushioning element, may be used as a form of “training” system to allow a person to become accustomed to the sensation of wearing and using a mask. A foam-cushion based mask may provide an initially more appealing and comfortable surface for a new patient than a gel or silicone-based cushion. The patient may subsequently switch from the foam-based cushion to a silicone or gel based cushion. In this way, the patient may be more likely to adhere to therapy because they are used to the very soft comfortable feeling of foam.

[0044] When applied to respiratory equipment, the cushioning element is adapted for connection with a mask frame. In use, an air-tight seal is formed between the cushioning element and the frame. This arrangement could be used for both nasal and full-face masks.

[0045] For example, Fig. 1 illustrates a mask 10 including a mask frame 20 and a foam-based cushioning element 30 provided to the mask frame 20. As illustrated, the foam-based cushioning element 30 provides a foam interfacing portion 32 adapted to contact the patient's face in use. In this embodiment, the foam-based cushioning element 30 is adapted for use with an existing mask (e.g., ResMed's Mirage Quattro mask), which allows the patient to switch from the foam-based cushioning element 30 to the mask's existing silicone-based cushion if desired.

Dual Foam Layers

[0046] In one form of device in accordance with an embodiment of the invention, the foam-based cushioning element has two layers, i.e., an interfacing portion and a clip portion.

[0047] In an embodiment, the interfacing portion or cushion is constructed from a soft unskinned resilient viscoelastic polyurethane foam. Such a foam is disclosed in PCT Publication Nos. WO 2008/011682, published January 31, 2008, and WO 2008/070929, published June 19, 2008, each of which is incorporated herein by reference in its entirety. In one form, the resilient foam may be formed by a known method such as die cutting.

[0048] Figs. 4a to 4g show a foam-based cushioning element 230 according to an embodiment of the invention. As illustrated, the cushioning element 230 includes an interfacing portion or face-contacting portion 232 and a clip portion 234 provided to the interfacing portion 232. In this embodiment, the clip portion 234 is adapted for an

interference fit with a mask frame, and the width of the clip portion 234 is narrower than the width of the interfacing portion 232 (e.g., see Figs. 4e and 4g).

[0049] In the illustrated embodiment, both an inside surface and an outside surface of the foam interfacing portion 232 are die cut. This typically results in straight cut edges, much like a kitchen sponge. The cushion may therefore have a square cross section.

[0050] In an embodiment, the clip portion of the cushioning element may be constructed from a more rigid foam than the interfacing portion. For example, the clip portion may be formed from nitrogen blown polyethylene, or some other clean, biocompatible foam having a fine cell-structure. Alternatively, the clip portion could be made from some other polymer or rubber. In an embodiment, the clip portion is adapted to form a cushion-to-frame engagement mechanism and to form a structural support for the interfacing portion.

[0051] The two layers (i.e., the interfacing portion and the clip portion) may be adhered to one another using polyurethane hot melt glue. This arrangement provides a one piece cushioning element with an interfacing portion adapted to engage the patient's face and a clip portion adapted to interface with the mask frame.

Cushion-to-Frame Engagement Mechanisms

[0052] According to an aspect of the invention, the cushion-to-frame engagement and connection mechanism provided by the clip portion may include a channel-type engagement or rib-type engagement.

[0053] As shown in Fig. 2, the channel-type engagement includes a foam clip portion 34 that is adapted to be received within the channel 22 of a mask frame 20 with an interference fit. The foam clip portion 34 extends around the entire perimeter of the cushioning element so as to form an air-tight seal and retention with the mask frame.

[0054] As shown in Figs. 3a to 3c, the rib-type engagement includes a foam clip portion 34 with one or more slots 38 to receive inner and/or outer ribs 23, 24 of the mask frame 20. For example, the slot to rib engagement may provide an inner frame rib engagement (see Fig. 3a), an outer frame rib engagement (see Fig. 3b), or an inner and outer frame rib engagement (see Fig. 3c). This arrangement provides a broader base of support for the sealing foam.

[0055] Figs. 5a and 5b illustrate a foam-based cushioning element 830 including a foam interfacing portion 832 and a clip portion 834, and Fig. 5c illustrates the cushioning element 830 provided to a mask frame 20. As shown in Figs. 5a and 5b, the clip portion 834 includes a slot 838 adapted to receive a rib of the mask frame 20. Also, providing a wider clip portion 834 allows more stiffness and structural integrity to be provided to the clip portion, making the clip portion easier to assemble to the mask frame.

[0056] When structured to form an interference fit with the mask frame, the clip portion may have the following properties: appropriate rigidity (e.g., less than that of the frame and in one form more rigid than the foam interfacing portion); non-porous; and/or low compression set (the amount of deformation expressed as a percentage of original dimensions) which a material retains after compressive stress is released (in this way, the clip portion maintains its retention force during its usage life).

Interfacing Portion Support Structure

[0057] In accordance with an embodiment of the invention, a range of different arrangements of clip portions and foam interfacing portions may be provided. For example, the width of the clip portion may match the interfacing portion, the width of the clip portion may be less than the width of the interfacing portion, or the width of the clip portion may be greater than the width of the interfacing portion.

[0058] When the width of the clip portion is less than the width of the interfacing portion, the clip portion and interfacing portion may be arranged such that (i) the outer perimeter of the clip portion and interfacing portion align (hides hardness of clip portion and provides desired freedom of movement in the interfacing portion), (ii) the inner perimeter of the clip portion and the interfacing portion align, or (iii) neither the inner or outer perimeter of the clip portion and the interfacing portion align.

[0059] Similarly, when the width of the clip portion is greater than the width of the interfacing portion, the clip portion and interfacing portion may be arranged such that (i) the outer perimeter of the clip portion and interfacing portion align, (ii) the inner perimeter of the clip portion and interfacing portion align, or (iii) neither the inner or outer perimeter of the clip portion and the interfacing portion align.

[0060] In these different configurations with different relative widths, the clip portion provides different forms of support of the interfacing portion.

[0061] When the width of the clip portion is less than the width of the interfacing portion and the outer perimeter of the clip portion aligns with the interfacing portion, the interfacing portion is more free to flex in regions not having a clip portion next to it than in regions having a clip portion adjacent to it. For example, where the interfacing portion overhangs the clip portion, that overhanging region of the interfacing portion has more freedom to move. This arrangement can be more comfortable and more able to adapt to different geometries of a person, and provide the correct vectors to seal the interfacing portion against the face.

[0062] When used as part of a respiratory mask, it may be preferable that the inner portion of the interfacing portion overhang the clip portion. In this arrangement in use, the face of the patient may engage with an unsupported inner edge of the softer interfacing portion causing it to bend and conform to the individual patient's shape.

[0063] Fig. 7a shows an elevation view detail from the frame side of the cushioning element 230 shown in Fig. 4e in a nasal bridge region. As shown in cross-section in Fig. 7b, it is apparent that the width w_2 of the clip portion 234 is less than the width w_1 of the interfacing portion 232 and that the outer perimeter of the clip portion 234 and the interfacing portion 232 are aligned. An advantage of this arrangement is illustrated in Fig. 7c where in use the nose is able to push the inner perimeter of the interfacing portion 232 in the direction shown by the arrow, in a cantilever manner as well as compressing.

[0064] Fig. 8 is a cross-section showing the clip portion 234 of the cushioning element 230 received within the channel 22 of a mask frame 20. It can be seen that the width of the clip portion 234 is less than that of the interfacing portion 232, and that the outer perimeter surfaces 236 and 238 respectively of the clip portion 234 and interfacing portion 232 are aligned while the respective inner perimeter surfaces 240, 242 are offset.

[0065] This arrangement is in contrast to prior art cushions (such as the Lifecare mask shown in Figs. 6a and 6b) where the inner perimeter of the cushion C abuts the frame F, and hence it is not free to move inwardly and can only compress.

[0066] In one form, a mask system may be provided that includes at least two different forms of cushioning element chosen from the set of foam-based cushion, silicone-based cushion, and gel-based cushion.

[0067] While the invention has been described in connection with what are presently considered to be the most practical and preferred embodiments, it is to be understood that the invention is not to be limited to the disclosed embodiments, but on the contrary, is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the invention. Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. Further, each independent feature or component of any given assembly may constitute an additional embodiment. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.

WHAT IS CLAIMED IS:

1. A cushion for a respiratory mask comprising a clip portion and an interfacing portion wherein the interfacing portion is constructed from a foam material and the clip portion is narrower than the interfacing portion.
2. The cushion as claimed in claim 1, wherein the clip portion and interfacing portion are aligned at their outer perimeter.
3. The cushion as claimed in claim 1, wherein the inner perimeter of the interfacing portion is free to cantilever in use.
4. The cushion as claimed in claim 1, wherein the interfacing portion is impermeable to air.
5. The cushion as claimed in claim 1, wherein the interfacing portion is not impermeable to air, and has an air permeability in the range of about 0 to about 50L/s/m^2 .
6. A respiratory mask assembly comprising:
 - a frame having a channel; and
 - a cushioning element including a clip portion adapted for interference seal and retention in the channel and wherein the cushioning element further comprises an interfacing portion constructed from foam and having a wider width than the clip portion.
7. A respiratory mask assembly comprising:
 - a frame having a channel; and
 - a removably replaceable interfacing structure including a clip portion adapted for interference seal and retention in the channel and wherein the interfacing structure further comprises a cushion component constructed from foam.
8. A mask system, comprising:

a common frame; and

at least a first cushion constructed from foam and a second cushion constructed from silicone, the first and second cushions each structured to removably attach to the frame.

9. A mask system according to claim 8, further comprising a third cushion constructed from gel and structured to attach to the frame.

10. A mask system according to claim 8, wherein the frame includes a channel and the first and second cushions each include a clip portion adapted for interference seal and retention in the channel.

11. A mask system according to claim 8, wherein the first cushion includes a cushioning element constructed from a soft unskinned resilient viscoelastic polyurethane foam.

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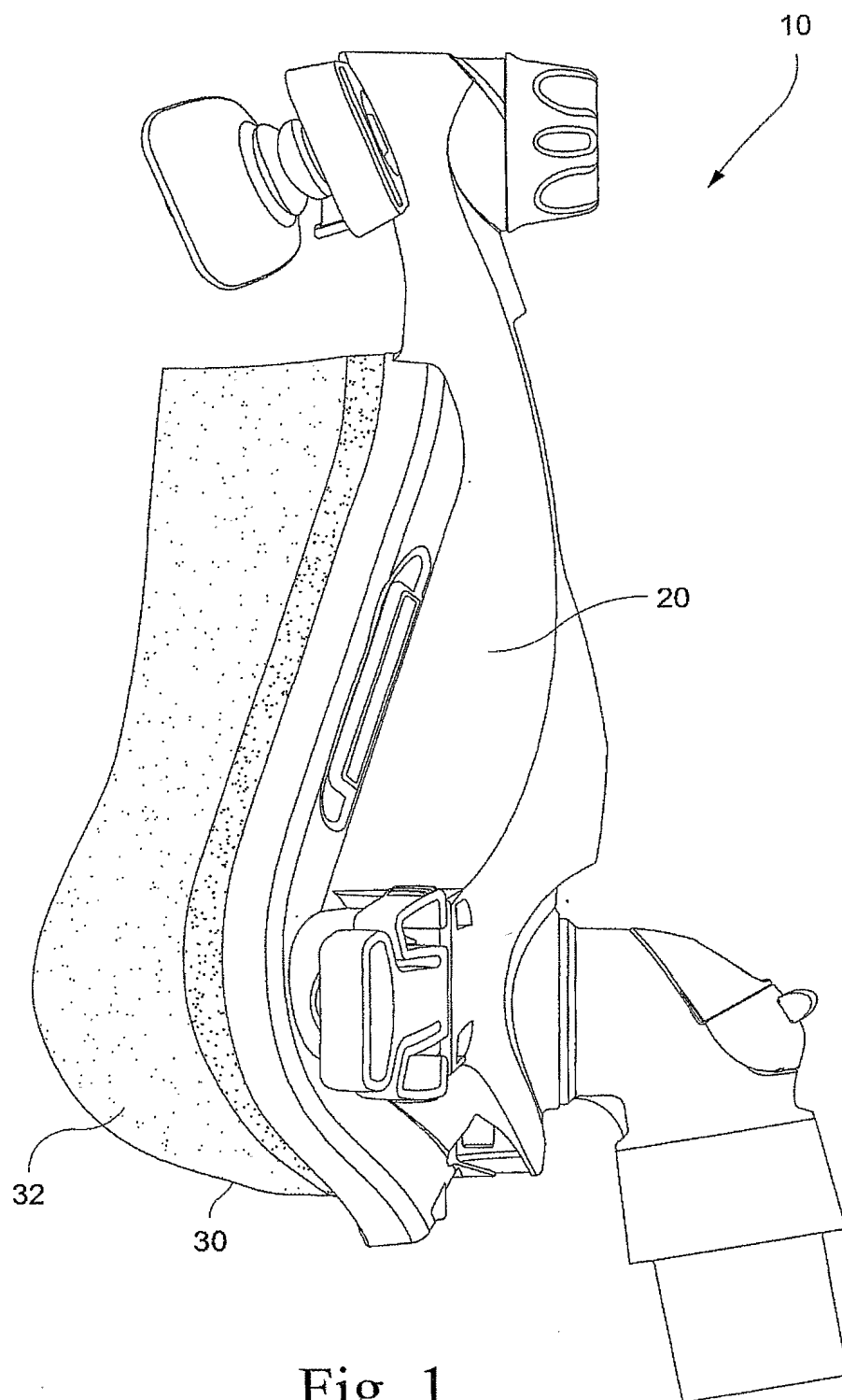


Fig. 1

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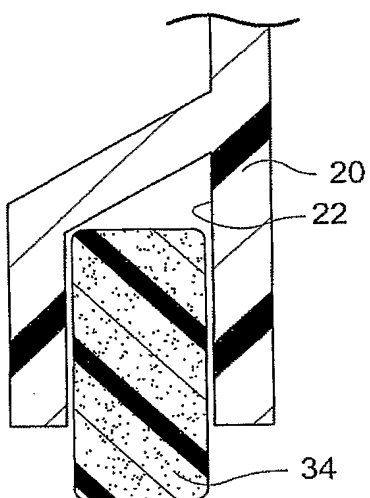


Fig. 2

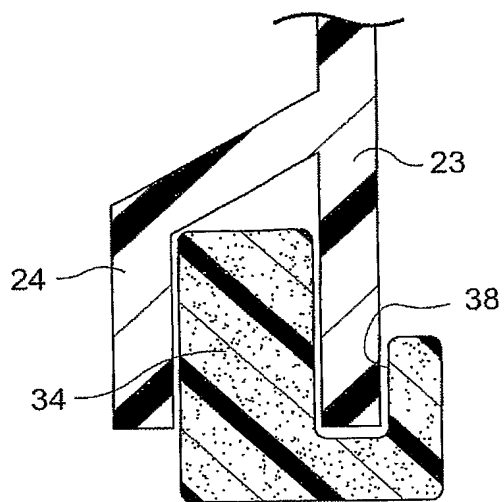


Fig. 3a

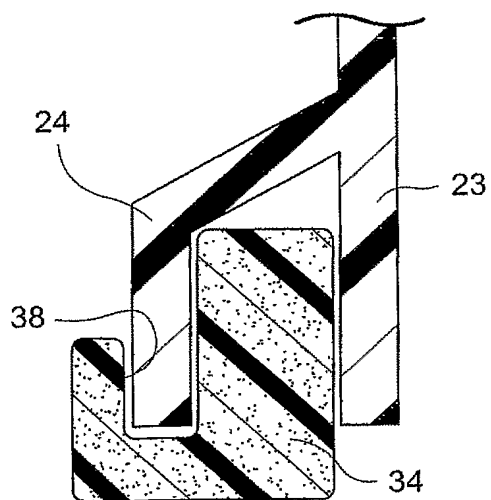


Fig. 3b

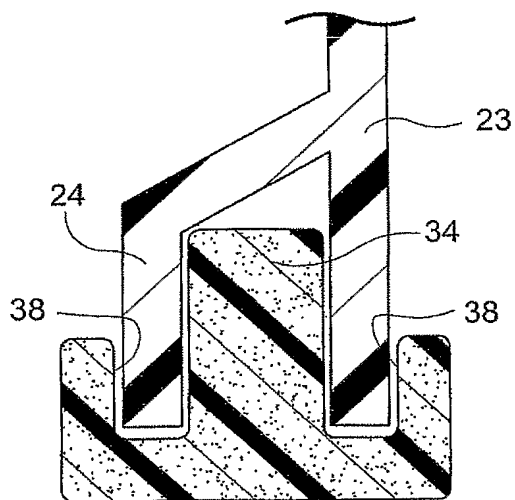


Fig. 3c

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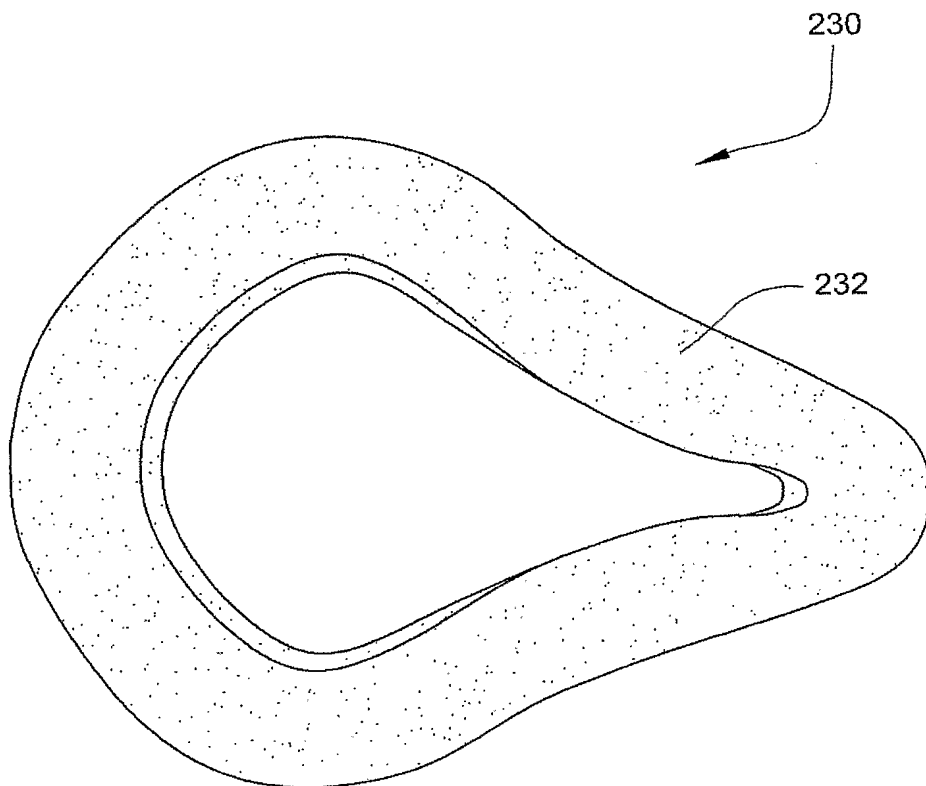


Fig. 4a

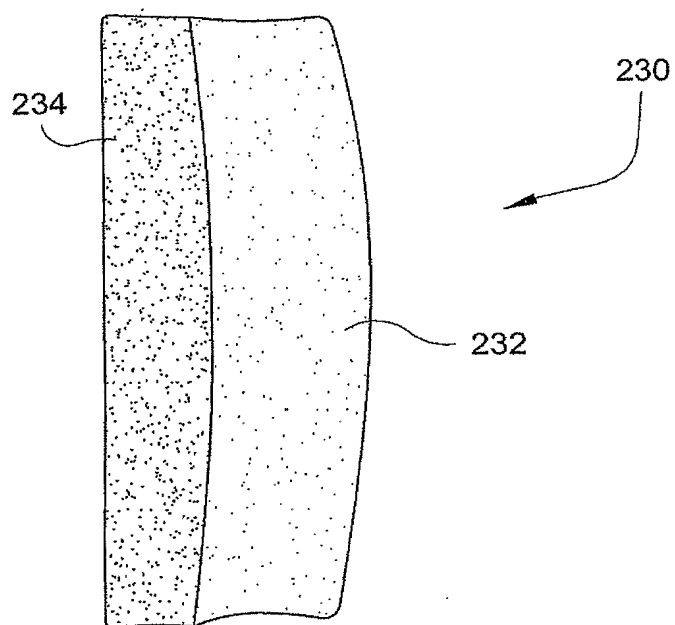


Fig. 4b

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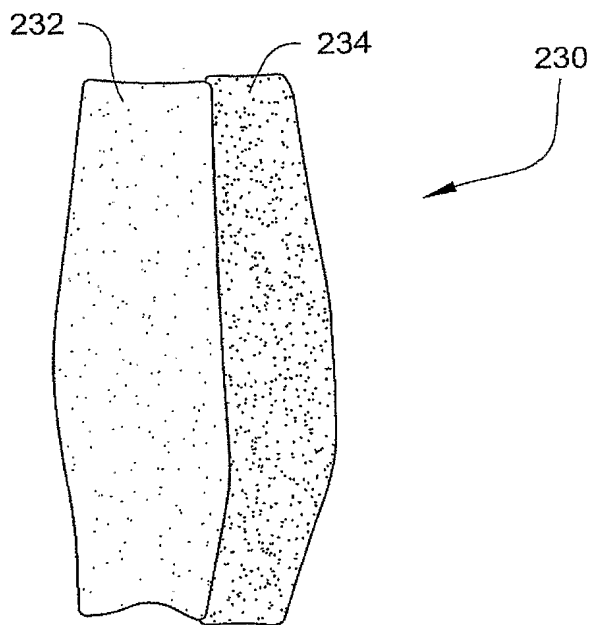


Fig. 4c

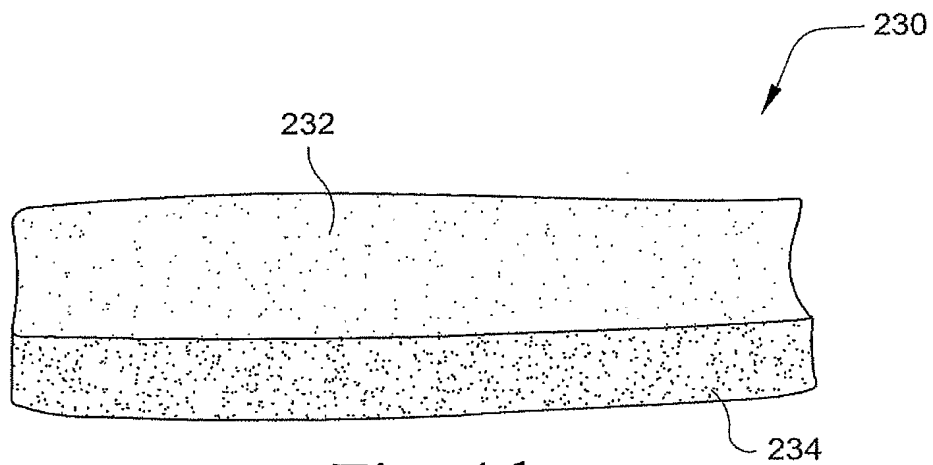


Fig. 4d

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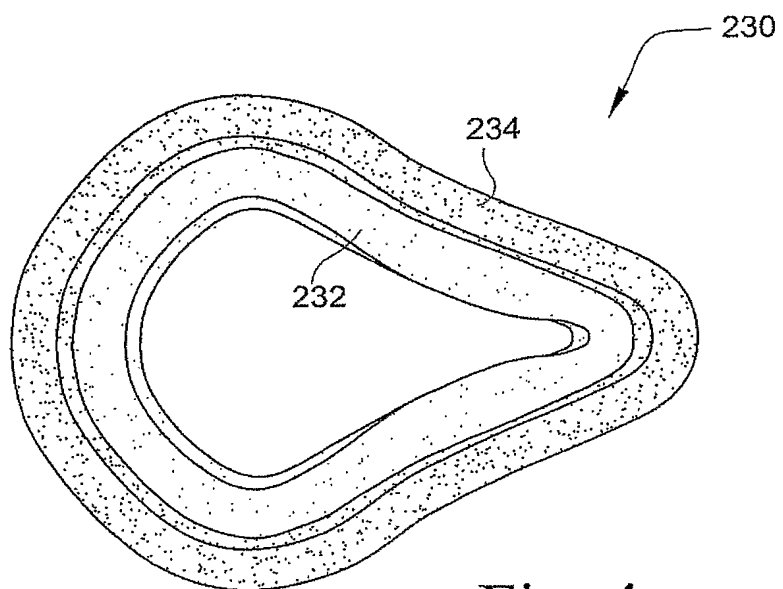


Fig. 4e

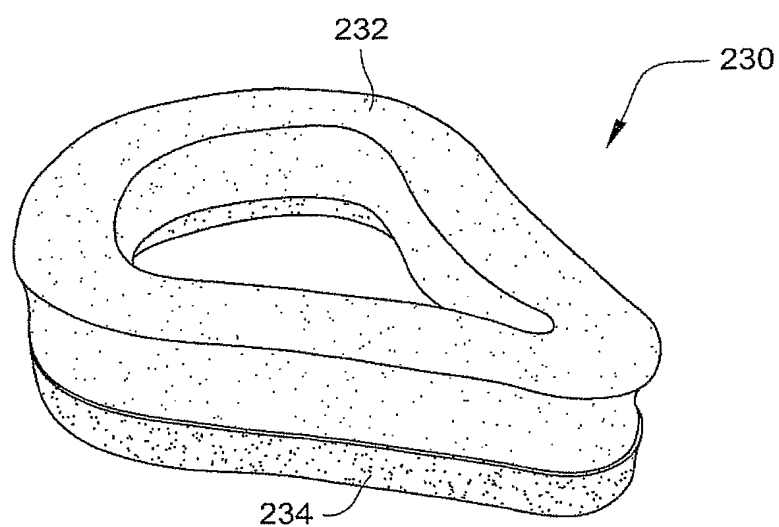


Fig. 4f

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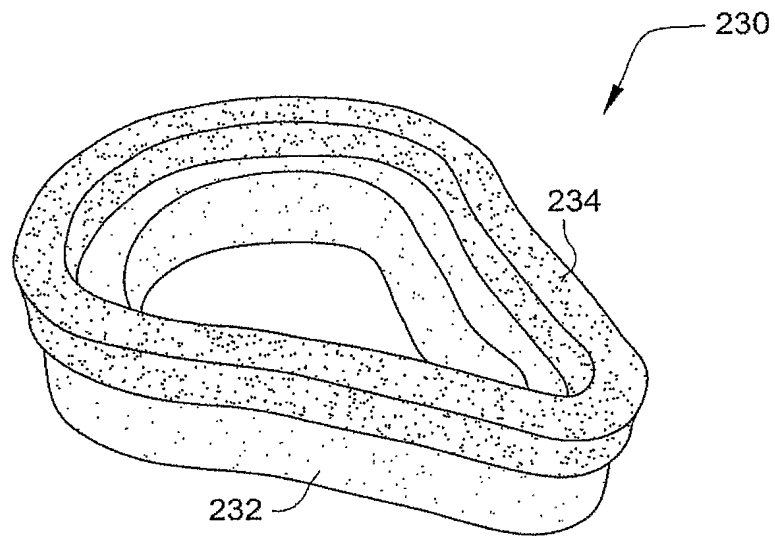


Fig. 4g

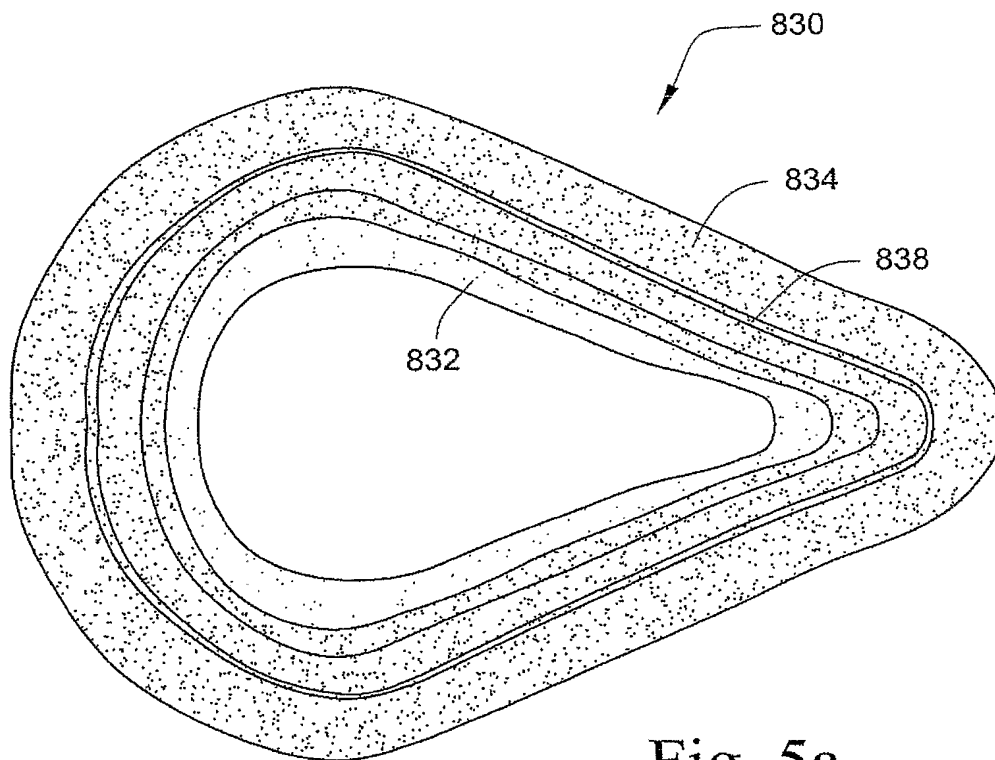


Fig. 5a

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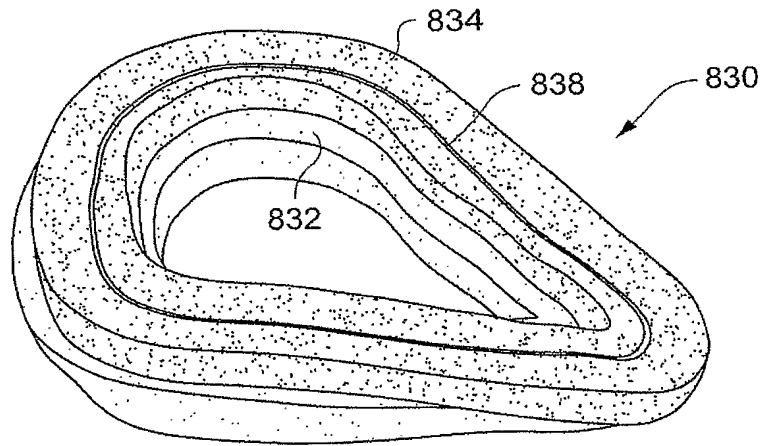


Fig. 5b

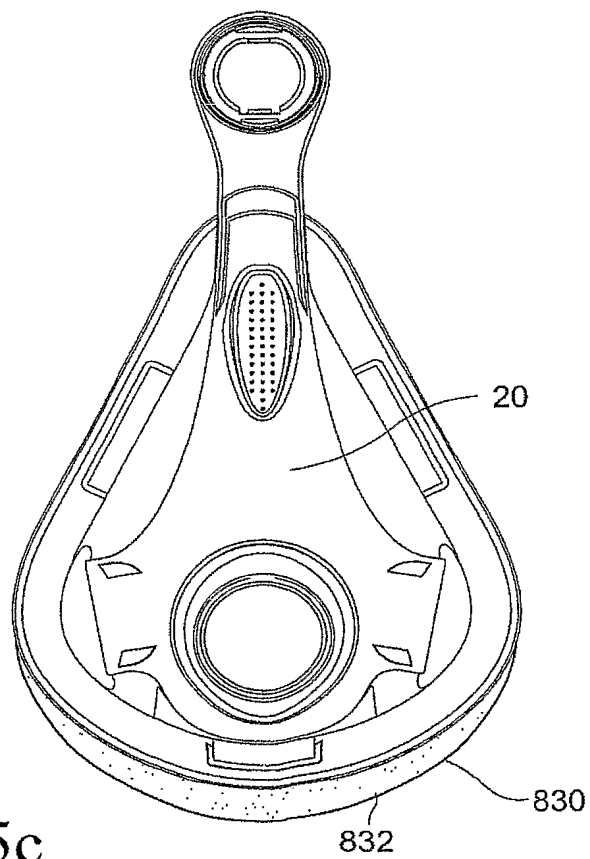


Fig. 5c

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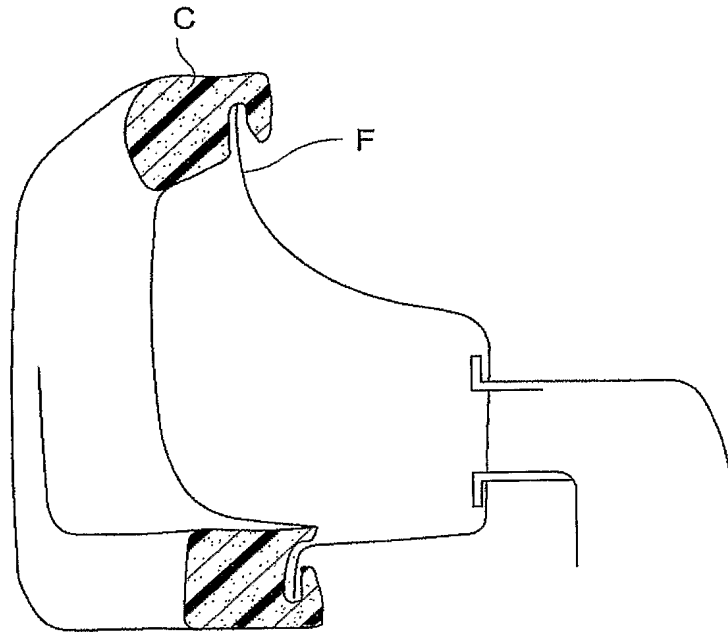


Fig. 6a
(PRIOR ART)

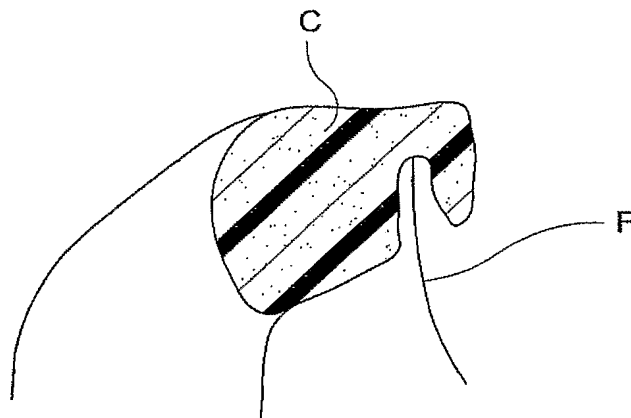


Fig. 6b
(PRIOR ART)

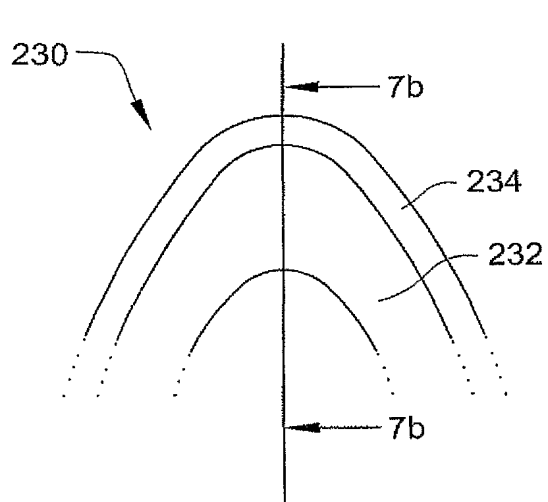


Fig. 7a

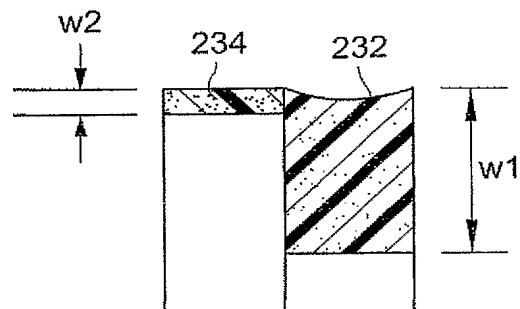


Fig. 7b

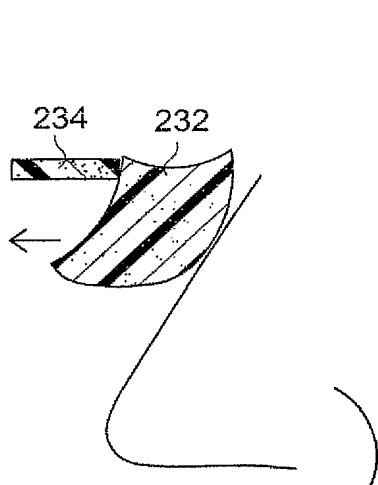


Fig. 7c

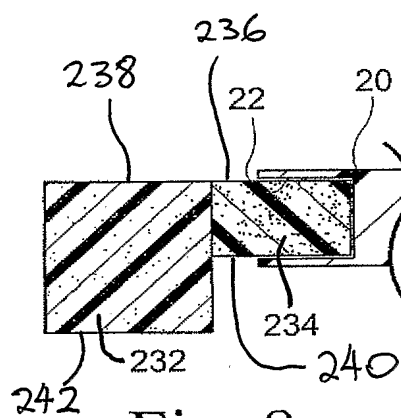


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2009/000262

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/06 (2006.01)

A62B 9/00 (2006.01)

A62B 7/00 (2006.01)

A62B 18/08 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

GOOGLE, PATENT LENS, EPOQUE: EPODOC & WPI: IPC & EC: A61M 16/-, A62B 7/-, A62B 9/-, A62B 18/- and Keywords (Mask, Respiratory, Apnoea, Snoring, Cushion, Support, Pad, Foam, Sponge) and similar terms.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6412487 B1 (GUNARATNAM et al.) 02 July 2002 See Abstract, Col.4 – Lines 18-20, Figs.6a-6e, Col.2 – Lines 28-41	1-7
X	US 7021311 B2 (GUNARATNAM et al.) 04 April 2006 See Abstract, Col.5 – Lines 28-30, Figs. 6a-6e, Col.5 – Lines 39-48	1-7
X	US 7207334 B2 (SMART) 24 April 2007 See Abstract, Col.2 – Lines 43-50, Col.3 – Lines 17-21	1-7
X	US 2003/0075180 A1 (RAJE et al.) 24 April 2003 See Abstract, Para [0011], Para [0231], Para [0183]	1-7

☒ Further documents are listed in the continuation of Box C

☒ See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
01 June 2009

Date of mailing of the international search report
09 JUN 2009

Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaustalia.gov.au
Facsimile No. +61 2 6283 7999

Authorized officer:
VARUN WADHWA
AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No : +61 2 6225 6142

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2009/000262

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box I

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-7

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2009/000262

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0118406 A1 (LITHGOW et al.) 24 June 2004 See Abstract, Figs. 8-8B, 11-11B, Para [0118], Figs. 1-5B	1-7
X	WO 2005/118040 A1 (RESMED LIMITED) 15 December 2005 See Abstract, Para [0010], [0024] & [0028]	1-7
P,X	US 2008/0257354 A1 (DAVIDSON et al.) 23 October 2008 See Whole Document	1-7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2009/000262

Supplemental Box I

(To be used when the space in any of Boxes I to IV is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1-7 are directed to a cushion for a respiratory mask. It is considered that the clip portion and an interfacing portion wherein the interfacing portion is constructed from a foam material and the clip portion is narrower than the interfacing portion comprises a first distinguishing feature.
- Claims 8-11 are directed to a mask system comprises a common frame and at least a first cushion constructed from foam and a second cushion constructed from silicone. It is considered that the first and second cushions each structured to removably attach to the frame comprise a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

Each of the abovementioned groups of claims has a different distinguishing feature and they do not share any feature which could satisfy the requirement for being a special technical feature. Because there is no common special technical feature it follows that there is no technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a priori*.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2009/000262

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
US	6412487	AU	12454/97	AU	14892/00
		AU	16811/02	AU	26505/00
		AU	42476/99	AU	49012/00
		AU	52007/00	AU	2004205283
		CA	2298129	CA	2470671
		DE	29724224U	EP	0956069
		EP	1187647	EP	1187648
		EP	1187650	EP	1479406
		EP	1621225	EP	1625868
		EP	1640034	EP	1741461
		HK	1071083	JP	2000279520
		JP	2005111287	JP	2006061703
		NZ	526165	NZ	526166
		NZ	526168	NZ	542849
		NZ	556540	US	6112746
		US	6374826	US	6439230
		US	6513526	US	6532961
		US	6634358	US	6691707
		US	6796308	US	6860269
		US	7021311	US	7066178
		US	7089939	US	7174893
		US	7185652	US	7207334
		US	7243651	US	7487777
		US	2002/0005198	US	2002/0005200
		US	2002/0023650	US	2002/0029781
		US	2002/0083948	US	2002/0096176
		US	2002/0108613	US	2002/0153012
		US	2002/0174867	US	2002/0174868
		US	2004/0025881	US	2004/0094159
		US	2004/0134497	US	2005/0022818
		US	2006/0107960	US	2006/0130843
		US	2006/0201515	US	2006/0289010
				AU	16355/00
				AU	34293/97
				AU	52005/00
				CA	2261790
				CA	2519452
				EP	1027905
				EP	1187649
				EP	1525895
				EP	1637175
				EP	1985327
				JP	2004041779
				NZ	513052
				NZ	526167
				NZ	543939
				US	6357441
				US	6491034
				US	6581602
				US	6701927
				US	6871649
				US	7069933
				US	7178527
				US	7234466
				US	7523753
				US	2002/0023649
				US	2002/0074001
				US	2002/0104540
				US	2002/0157672
				US	2003/0034034
				US	2004/0099272
				US	2006/0076017
				US	2006/0144405
				US	2007/0107735

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

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